REMARKS

This responds to the Office Action dated May 9, 2003. Claim 3 is amended. No claims are canceled or added. As a result, claims 2-35 are now pending in this application.

Applicant appreciates the Examiner's further amplification of the bases of rejection. For brevity, Applicant reiterates the arguments previously made of record in Applicant's Feb. 10, 2003 Response to the November 8, 2002 Office Action. Those arguments are incorporated herein by reference. This Response addresses the further explanations provided in the May 9, 2003 Office Action.

§102 Rejection of the Claims

1. Claims 4 – 6 were rejected under 35 U.S.C § 102(b) as allegedly anticipated by Yerich et al. (U.S. Patent No. 5,562,711). However, claims 4 - 6 presently recite or incorporate using a baseline portion of the thoracic impedance, the baseline portion associated with a fluid shift away from the thorax. Applicant can find no such disclosure in the cited portions of Yerich et al., which apparently uses a higher frequency respiration component of thoracic impedance, as discussed in Applicant's previous response. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection.

2. Claims 1 – 12 and 15 – 35 were rejected under 35 U.S.C. § 102(b) as allegedly anticipated by Combs et al. (U.S. Patent No. 5,957,861). Claims 1 – 8, 15 – 20 and 30 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Pitts Crick et al. (U.S. Patent No. 6,104,949). Claims 1 – 8, 13 – 20 and 30 were rejected under 35 U.S.C. § 102(e) as allegedly anticipated by Erlebacher et al. (U.S. Patent No. 6,473,640). Applicant traverses.

The cited portions of Combs et al., Pitts Crick et al., and Erlebacher et al. all relate to edema, that is, fluid accumulation in the lungs. By contrast, the present claims all relate to hypotension, that is, a fluid shift away from the thorax, rather than any fluid shift toward the thorax associated with edema. Therefore, Combs et al., Pitts Crick et al., and Erlebacher et al. all fail to disclose—and actually expressly teach away from the present claims, which relate to providing a therapy in response to detection of a fluid shift away from the thorax.

The present patent specification emphasizes that hypotension (fluid shift away from the thorax) is distinguishable from edema (involving a fluid shift toward the thorax):

> One problem faced by some patients is hypotension, that is, low blood pressure. Hypotension can result in dizziness, sometimes referred to as presyncope. Hypotension can even lead to unconsciousness, sometimes referred to as syncope. One cause of hypotension is an excess shifting of blood in the circulatory system toward the extremities (arms and legs) and away from vital organs in the patient's head and thorax. This can occur, for example, when the patient changes posture from lying horizontal or sitting with legs elevated to a position in which the patient is sitting or standing erect. Hypotension resulting from such changes in posture is referred to herein as orthostatic hypotension. However, hypotension may also have causes other than changes in posture. For example, maintaining the same posture for an extended period of time (e.g., sitting erect during an intercontinental airplane flight) may also cause hypotension.

(Application at pages 2 – 3). Applicant respectfully submits that any disclosure of providing a therapy in response to edema (involving a fluid shift toward the thorax) is different—and actually teaches away from—providing a therapy in response to hypotension (involving a fluid shift away from the thorax). Accordingly, Applicant respectfully requests withdrawal of these bases of rejection of these claims.

As an additional note, regarding the rejection's specific assertion that Pitts Crick et al. "discloses a medical device that increased the rate of pacing stimuli based at least in part on an increase in the baseline portion of thoracic impedance" (Office Action ¶ 4), Applicant disagrees. Applicant has carefully reviewed the cited portions of Pitts Crick et al., which apparently measures an impedance difference that "indicates the degree of fluid which masses in the thoracic region. . . i.e., the degree to which the patient has congestive heart failure" (Pitts Crick et al. at column 6, lines 21-22.) Pitts Crick et al. further states that "[i]f the difference is larger than x, a moderate degree of heart failure is assumed and a therapy is delivered." (Pitts Crick et al. at column 6, lines 26-28.) Importantly, Pitts Crick et al. notes that a lower baseline trans-thoracic impedance corresponds to more severe congestive heart failure. (*See* Pitts Crick et al. at column 5, line 66 to column 6, line 4.) Therefore, Pitts Crick et al.'s treatment of edema/CHF corresponds to providing a therapy in response to a decrease in baseline thoracic impedance, rather than an increase in baseline thoracic impedance.

3. Claims 13 and 14 were rejected under 35 U.S.C. § 102(b) as being anticipated by Sheldon et al. (U.S. Patent No. 6,044,297). Applicant traverses.

Sheldon et al. apparently discloses an implantable medical device capable of detecting postural changes. However, Applicant can find no disclosure in Sheldon et al. of detecting hypotension, or of detecting hypotension regardless of whether the hypotension is postural in nature, or of providing a therapy in response to detected hypotension—even when the detected hypotension is not postural in nature. Instead, Sheldon et al. apparently merely increases pacing rate, "for example switching from a pacing rate of 50 when the patient is sitting to a rate of 70 upon a clear indication of the patient moving to a standing position"—even when hypotension is not present. (*See* Sheldon et al. at column 7, lines 17-60.)

By contrast, the present patent application explains:

> hypotension may also have causes other than changes in posture. For example, maintaining the same posture for an extended period of time (e.g., sitting erect during an intercontinental airplane flight) may also cause hypotension.

(Application at page 2.) Because hypotension may be both postural or non-postural in origin, the Applicant has recognized that it is desirable to treat both such types of hypotension. Claims 13 and 14 recite detecting both a hypotension associated with a change in a subject's posture and a hypotension that is not associated with a change in the subject's posture, and providing a therapy to the subject's heart based on the detected hypotension. Because Sheldon et al. fails to disclose detecting hypotension, and further fails to disclose detecting both postural and non-postural hypotension, and still further fails to disclose treating both postural and non-postural hypotension, Applicant respectfully submits that these claims are not anticipated by Sheldon et al. Accordingly, Applicant respectfully requests withdrawal of this basis of rejection of these claims.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (612-373-6951) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743

Respectfully submitted,

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Date Aug. 8, 2003

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on this 8 day of August, 2003.

GREG HANSON
Name

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